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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/479,995	06/07/1995	ROBERT G. PERGOLIZZI	ENZ-(D1)(C2)	8797
28171	7590	07/15/2005	EXAMINER	
ENZO BIOCHEM, INC. 527 MADISON AVENUE (9TH FLOOR) NEW YORK, NY 10022			MARSCHER, ARDIN H	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 07/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Interview Summary</b>	Application No.	Applicant(s)	
	08/479,995	PERGOLIZZI ET AL.	
	Examiner	Art Unit	
	Ardin Marschel	1631	

All participants (applicant, applicant's representative, PTO personnel):

(1) Ardin Marschel (Exr.)

(3) Gene Rzucidlo (Appl. Rep.)

(2) Ronald Fedus (Appl. Rep.)

(4) Rob Schulman (Appl. Rep.)

Date of Interview: 29 June 2005

(5) Michael Woodward (Exr.)

Type: a) ☐ Telephonic b) ☐ Video Conference

c) ☒ Personal [copy given to: 1) ☐ applicant 2) ☒ applicant's representative]

Exhibit shown or demonstration conducted: d) ☒ Yes e) ☐ No.

If Yes, brief description: See attached

Claim(s) discussed: all rejected.

Identification of prior art discussed: as in Final Off. Action, mailed 5/27/05.

Agreement with respect to the claims f) ☐ was reached. g) ☒ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See summary below.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

We discussed possible written support for di- & tri- nucleotide sequences as in claim 516, for example. We discussed hormone receptor basis in our disclosure to claim dependence change. We discussed 112, 2nd, as to claim amending to give proper antecedent basis. We discussed the prior art rejections.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Ardin Marschel  
Examiner's signature, if required

## Summary of Record of Interview Requirements

### Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

### Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

#### Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

#### 37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,  
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

### Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

**Combination of Segments (Dinucleotide or Trinucleotide Repeat) in Claims 516 & 522**

CLAIM 516. (Pending) A DNA molecule which carries a polynucleotide sequence complementary to a gene sequence or portion thereof of a nucleic acid containing organism, and which further carries a polynucleotide portion which comprises a repeating low-complexity polynucleotide sequence of a dinucleotide repeat or a trinucleotide repeat.

CLAIM 524. (Pending) The DNA molecule of claim 522, further carrying a polynucleotide portion which comprises a repeating low complexity polynucleotide sequence of a dinucleotide repeat or a trinucleotide repeat.

**Enz-11(C2)(D1)(C2)**

Combination of Segments (Dinucleotide or Trinucleotide Repeat) in Claims 516 & 522

CLAIM 516. (CURRENTLY AMENDED) The A DNA molecule of ~~claim 512~~, further carrying which carries a polynucleotide sequence complementary to a gene sequence or portion thereof of a nucleic acid containing organism, and which further carries a polynucleotide portion which comprises a repeating low-complexity polynucleotide sequence of a dinucleotide repeat or a trinucleotide repeat.

CLAIM 524. (CURRENTLY AMENDED) The DNA molecule of claim 522, further carrying a polynucleotide portion which comprises a repeating low complexity polynucleotide sequence of a dinucleotide repeat or a trinucleotide repeat ~~selected from the group consisting of poly dGT, poly dAC, poly dCT, poly dAT, poly dGC, poly dGA, poly dG, poly dC, poly dT, poly dA, and any combination thereof.~~

Enz-11(C2)(D1)(C2)

Combination of Segments (Dinucleotide or Trinucleotide Repeat) in Claims 516 & 522

Support for (repeating low complexity polynucleotide sequence of a dinucleotide repeat or a trinucleotide repeat is found in the '995 specification:

Page 15, first paragraph

It is thus preferred to choose polynucleotide sequence portions on the bridging entity which are non-coding, and not likely to be complementary to sequences on the analyte such as, for example, sequences comprising poly deoxy G, poly deoxy A, *poly deoxy GT, poly deoxy GA, poly deoxy GAT, poly deoxy GTA*, or any other *low complexity (repeating) sequence*.

Page 27, first paragraph

If the polynucleotide sequence comprises a strand of any one nucleotide (e.g., poly dG or poly dC) or a strand of *any dinucleotide repeat (e.g., poly dGT, or the like)*, the same can be readily prepared by enzymatic-based reactions such as by using DNA polymerase, or by synthetic methodology.

Page 58, Example 32

2. *pd(G-T)<sub>5</sub> and pd(A-C)<sub>5</sub>* are provided and hybridized to form a perfect double-strand.

The ends must be perfectly matched. In order to obtain this condition it is necessary to use high C<sub>0</sub>t conditions for hybridization.

Enz-11(C2)(D1)(C2)

4. The ligation products are isolated. They are double-stranded *poly d (G-T) poly d (A-C)*. (*Any complementary, repeating, low complexity sequence can be used*. The subsequent modification and chemistries must be adjusted accordingly.)

Original Claim 78

A DNA molecule carrying a polynucleotide portion which comprises a sequence selected from the group consisting of *poly dGT, poly dAC, poly dCT, poly dAT, poly dGC, poly dGA, poly dG, poly dC, poly dT, poly dA*, and a *repeating low-complexity polynucleotide*.

Original Claim 90

The DNA molecule of any of Claims 88 or 89 which carries a polynucleotide portion which comprises a sequence selected from the group consisting of *poly dGT, poly dAC, poly dCT, poly dAT, poly dGC, poly dGA, poly dG, poly dC, poly dT, poly dA*, and a *repeating low-complexity polynucleotide*.

\* \* \* \* \*

**Hormonal Receptor Covalently Attached to Polynucleotide Sequence in Claim 510**

CLAIM 510. (Pending) A polynucleotide sequence covalently attached to a hormonal receptor.

Support for hormonal receptor covalently attached to polynucleotide sequence in Claim 510 is found in the '995 specification:

Page 12, last fourteen lines

*A molecularly recognizable portion on an analyte may be, for example, a polynucleotide sequence, such as RNA or DNA, to be recognized by its complementary sequence; an antigen portion, to be recognized by its corresponding monoclonal or polyclonal antibody; an antibody portion, to be recognized by its corresponding antigen; a lectin portion, to be recognized by its sugar; a sugar portion, to be recognized by its lectin; a hormone portion, to be recognized by its receptor; a receptor portion, to be recognized by its hormone; an inhibitor portion, to be recognized by its enzyme; an enzyme portion, to be recognized by its inhibitor; a cofactor portion, to be recognized by a cofactor enzyme binding . . .*

**Enz-11(C2)(D1)(C2)**



Page 13, last paragraph, through Page 14, first paragraph

The portion on the bridging entity capable of recognizing the molecularly recognizable portion on the analyte must contain a molecule or molecular fragment complementary to the recognizable portion on the analyte. Therefore, if the analyte contains a polynucleotide sequence, the recognizing portion of the bridging entity should be complementary polynucleotide sequence or "probe". If the molecularly recognizable portion on the analyte is a generalized antigen, the recognizing portion on the bridging entity should be an antibody thereto. *The same is true with respect to the complementary pairs* sugar/lectin, *receptor/hormone*, inhibitor/enzyme, and the like, described previously.

Page 15, last paragraph

Specific examples of bridging entities as used in this invention are covalently attached entities of monoclonal or polyclonal antibodies with polynucleotides, polynucleotides with polynucleotides, protein antigens with polynucleotides, saccharides with polynucleotides, small molecular weight organic compounds with polynucleotides, lectins with polynucleotides, *receptors with polynucleotides, hormones with polynucleotides*, enzyme inhibitors with polynucleotides, enzyme cofactors with polynucleotides, and combinations and permutations thereof.

Original Claim 12

The method of Claim 1 wherein said recognizing portion on said bridging entity comprises a *hormone*.

Original Claim 13

The method of Claim 1 wherein said *recognizing portion on said bridging entity comprises a receptor*.

Original Claim 15

The method of Claim 1 wherein said *recognizing portion on said bridging entity comprises an enzyme active site, a cofactor binding site, or a receptor protein*.

Original Claim 25

The method of Claim 1 wherein said *polynucleotide sequence in said bridging entity is covalently attached to a hormone*.

Original Claim 26

The method of Claim 1 wherein said *polynucleotide sequence in said bridging entity is covalently attached to a receptor*.

Original Claim 76

*A polynucleotide sequence covalently attached to a receptor.*

Original Claim 77

*A polynucleotide sequence covalently attached to a hormone.*

\* \* \* \* \*

Enz-11(C2)(D1)(C2)



**Dependency Changes in Claims 366, 370, 374-375, 379, 384, 392-393, 397, 402 & 408**

***Dependency Changes Effectuated in April 29, 2004 Amendment***

366. (CURRENTLY AMENDED) The process according to claim ~~363~~ 443, wherein detecting is directly carried out by means of a detectable signal provided by said signal generating portion.

CLAIM 370. (CURRENTLY AMENDED) The process according to claim ~~363~~ 443, wherein detecting is indirectly carried out by means of a detectable signal provided by said signal generating portion.

CLAIM 374. (CURRENTLY AMENDED) The process according to claim ~~363~~ 443, wherein said signal generating portion is capable of being detected by a member selected from the group consisting of an enzymatic measurement, a fluorescent measurement, a phosphorescent measurement, a chemiluminescent measurement, a colorimetric measurement, a microscopic measurement, an electron density measurement, a radioactive measurement and a binding step on an insoluble phase.

CLAIM 375. (CURRENTLY AMENDED) The process according to claim ~~363~~ 443, wherein the analyte is fixed or immobilized.

CLAIM 379. (CURRENTLY AMENDED) The process according to claim ~~363~~ 443, wherein the molecular bridging entity is immobilized.

**Enz-11(C2)(D1)(C2)**

CLAIM 384. (CURRENTLY AMENDED) The process according to claim 384 444, wherein detecting is directly carried out by means of a detectable signal provided by said signal generating portion.

CLAIM 388. (CURRENTLY AMENDED) The process according to claim 384 444, wherein detecting is indirectly carried out by means of a detectable signal provided by said signal generating portion.

CLAIM 392. (CURRENTLY AMENDED) The process according to claim 384 444, wherein said signal generating portion is capable of being detected by a member selected from the group consisting of an enzymatic measurement, a fluorescent measurement, a phosphorescent measurement, a chemiluminescent measurement, a colorimetric measurement, a microscopic measurement, an electron density measurement, a radioactive measurement and a binding step on an insoluble phase.

CLAIM 393. (CURRENTLY AMENDED) The process according to claim 384 444, wherein the analyte is fixed for immobilized.

CLAIM 397. (CURRENTLY AMENDED) The process according to claim 384 444, wherein the molecular bridging entity is immobilized.

CLAIM 402. (CURRENTLY AMENDED) The process according to claim 399 445, further comprising one or more washing steps prior to detection.

Enz-11(C2)(D1)(C2)

CLAIM 408. (CURRENTLY AMENDED) The process according to claim 405 446, further comprising one or more washing steps prior to detection.

Please note that claims 363, 381, 399 and 405 had been canceled. Thus, the above amendments to these twelve claims was necessary to correct improper dependencies upon canceled base claims.

\* \* \* \* \*

**Vagueness/Indefiniteness (Lack of Antecedent Basis) in Claims 522-525, 527 & 549**

CLAIM 522. (Pending) A circular DNA molecule covalently attached to a non-radiolabeled signal generating moiety capable of directly or indirectly providing a detectable signal, said direct signal providing signal generating portion being selected from the group consisting of a fluorogenic compound, a phosphorescent compound, a chromogenic compound, a chemiluminescent compound, an electron dense compound, an enzyme, and said indirect signal providing signal generating portion being selected from the group consisting of an antibody, an antigen, a hapten, a receptor, a ligand, an enzyme, a polynucleotide sequence capable of recognizing a signal-containing moiety, and a compound capable of binding to an insoluble phase.

CLAIM 522. (CURRENTLY AMENDED) A circular DNA molecule covalently attached to a non-radiolabeled ~~non-nucleotidyl~~ signal generating moiety capable of directly or indirectly providing a detectable signal, said direct signal providing signal generating portion being selected from the group consisting of a fluorogenic compound, a phosphorescent compound, a chromogenic compound, a chemiluminescent compound, an electron dense compound, an enzyme, and said indirect signal providing signal generating portion being selected from the group consisting of an antibody, an antigen, a hapten, a receptor, a ligand, an enzyme, a polynucleotide sequence capable of recognizing a signal-containing moiety, and a compound capable of binding to an insoluble phase.

Enz-11(C2)(D1)(C2)

The 5/27/05 Office Action stated that "Claim 522, lines 3-4, cites the phrase "said direct signal providing signal generating portion" which lacks antecedent basis due to no such "portion" being described previously in the claim. Clarification via clearer claim wording is requested. . .

CLAIM 522. (PROPOSED) A circular DNA molecule covalently attached to a non-radiolabeled signal generating moiety capable of directly or indirectly providing a detectable signal, wherein said direct directly detectable signal providing signal generating ~~portion-being~~ moiety is selected from the group consisting of a fluorogenic compound, a phosphorescent compound, a chromogenic compound, a chemiluminescent compound, an electron dense compound, an enzyme, and said indirect signal providing signal generating portion being selected from the group consisting of an antibody, an antigen, a hapten, a receptor, a ligand, an enzyme, a polynucleotide sequence capable of recognizing a signal-containing moiety, and a compound capable of binding to an insoluble phase.

\* \* \* \* \*

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Anticipation Rejection by Langer et al. (1982) of Claim 506

CLAIM 506. (Pending) A polynucleotide sequence covalently attached to an antibody.

\* \* \* \* \*

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